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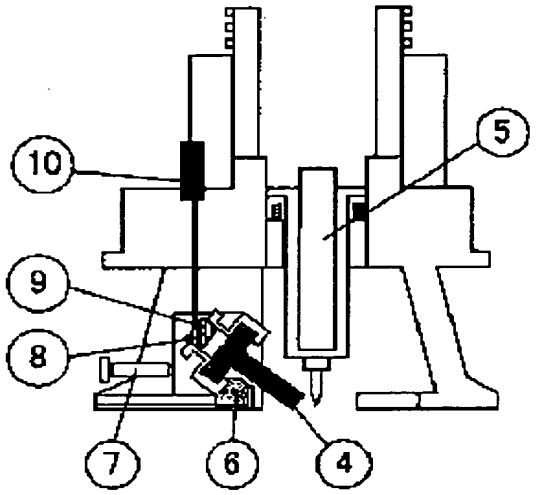
(54) DEVICE FOR MEASURING BODY FLUID COMPONENT

(57)Abstract:
PROBLEM TO BE SOLVED: To provide a device for measuring body fluid component having a puncture tool and a body fluid component measuring part, which can surely collect the leaked body fluid within a short time and can successively perform puncturing, collection of the body fluid, measurement and display of the result.
SOLUTION: The device for measuring body fluid component comprises a puncture needle, a body fluid collecting means for collecting the body fluid leaked from the skin by puncturing the skin with the puncture needle, and a body fluid component measuring means for measuring the body fluid component. The device for measuring body fluid component is characterized by that it further contains a position adjusting means for adjusting the body fluid collecting position of the body fluid collecting means.



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DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Field of the Invention] the specific component by which this invention is contained in body fluid, such as the blood sugar level, -- it can measure -- in addition -- and it is related with the body fluid component measuring instrument constituted so that it could display by actuation of one as a result of a puncture, body fluid extraction, and measurement.
[0002]
[Description of the Prior Art] In recent years, the diabetic is increasing rapidly from change of a living environment. A diabetic needs to maintain fluctuation of the everyday blood sugar level at the normal range, and the self-blood sugar level measurement (SMBG) to which the patient itself acts as the monitor of the self blood sugar level is recommended.
[0003] Blood is made to permeate the test paper which carries out coloration to one of the measuring methods of the blood sugar level according to the amount of blood glucose, and the approach of measuring the degree of the coloration optically and converting into the blood sugar level is used widely. Moreover, an enzyme electrode is used as an option, by contacting blood to a test piece, an enzyme reaction is made to cause and the approach of converting into the blood sugar level the anode current value generated through the electrochemical reaction is used.
[0004] After a patient does the puncture of the skins, such as a fingertip, with puncture implements, such as Lancet, on the occasion of colorimetric measurement, the blood which came out is made to permeate the test paper. A measuring device is equipped with this test paper, and the blood sugar level is calculated. Since the puncture implement and the blood sugar measuring instrument are separate, the conventional self-blood sugar level measuring instrument needs to carry out two actuation with the actuation which carries out the puncture of the skin, and the actuation in which blood is made to permeate the test paper, and is very difficult for an unfamiliar patient or the patient to whom eyesight fell. Then, that with which the puncture implement and blood sugar measuring instrument like the publication to JP,13-309905,A or JP,2000-116626,A as what is going to solve the above faults were united is developed.
[0005] Although blood collecting is performed on the other hand by the fingertip which the capillary generally concentrated in order to secure blood required for measurement, a fingertip is also the part which a nerve concentrates, and may serve as a burden of the patient at the time of blood collecting with a pain, and a health-care top -- a patient reduces a measurement count arbitrarily -- may also pose a problem. For the reason, the blood collecting instrument which it is little, and the equipment [amount / 1 time of / of blood collecting] which can be measured severalmicrol is indicated, and can be voted also on an arm with few pains in WO No. 43962 [97 to] official report as an option is also indicated by JP,9-304329,A.
[0006]
[Problem(s) to be Solved by the Invention] In order to measure blood sugar determination several times every day in many cases and to raise a patient's compliance, mitigation of a pain is a supreme proposition, it is blood volume little [how], and it is an important problem how blood is efficiently extracted from a part with few pains.
[0007] For example, with equipment given in JP,2001-309905,A, the approach of drawing in using

an electric rotary pump is indicated. However, in respect of equipment being enlarged from the need of equipping with a suction pump, and weight also becoming heavy, and calling it portability, it is not desirable. Furthermore, in order to use a cell for the source of power of an electric rotary pump, it is not desirable from the field of cost.
[0008] Furthermore, such a patient has large individual difference also about the description of blood, or a human form, and if there are some persons who can measure well also with the same equipment, there are also those who fail in measurement, and also when a puncture needs to be carried out also twice to one measurement, it is generated, and he causes a compliance fall.
[0009] The purpose of this invention is to offer the body fluid component measuring instrument which could be equipped with the puncture implement and the body fluid component test section, could display as a result of a puncture, body fluid extraction, and measurement, raised the certainty of measurement and was excellent in portability and a cost side by extracting the body fluid which bled continuously certainly [are a short time and].
[0010]
[Means for Solving the Problem] Following equipment was found out as a result of this invention person's inquiring wholeheartedly to this technical problem. That is, the body-fluid component measuring device characterized by to equip this invention with a justification means adjust the body-fluid extraction location of this body-fluid extraction means, in the body-fluid component measuring instrument equipped with a body-fluid extraction means extract the body fluid leaked by carrying out the puncture of the skin with the reusable puncture needle and this reusable puncture needle which carry out the puncture of the skin, and a body fluid component measurement means measure this amount of body fluid components is offered.
[0011] Moreover, this body fluid extraction means is a means to extract body fluid from body fluid extraction opening according to capillarity, and this invention offers the body fluid component measuring device characterized by equipping this justification means with the means to which this body fluid extraction opening is moved near the blood collecting section of the skin, and an elastic means to always energize to a skin side as an example of a mode.
[0012] Furthermore, as for this invention, this body fluid extraction means is equipped with a tube-like body fluid doner site by this justification means. When the body fluid extraction directions are gravity and the reverse sense, this justification means is a means to adjust the include angle of this body fluid doner site and the skin contact surface to ten - 50 degrees. Conversely, when the body fluid extraction direction is the gravity direction, the body fluid component measuring device characterized by this justification means being a means to adjust the include angle of this body fluid doner site and the skin contact surface to ten - 90 degrees is offered.
[0013] Moreover, this invention offers the body fluid component measuring device characterized by this justification means being a means to which the location of body fluid extraction opening of this body fluid extraction means is moved to the contact location at the time of total body water measurable [with this body fluid measurement means] leaking out from the skin.
[0014]
[Embodiment of the Invention] A blood sugar measuring device is explained to an example for the desirable operation gestalt of the body fluid component measuring device of this invention. This equipment is [0015]. [applicable not only to blood sugar determination but various body fluid component measuring devices] The body fluid component measuring instrument of this invention is a measuring instrument for measuring the specific component which is constituted so that it may be used equipping the folder part of this body with a body, a removable reusable puncture needle, and a removable measurement chip, carries out the puncture of the skin, extracts body fluid, and is contained in this. Into a body part, it has a detection device for detecting the puncture device for making the reusable puncture needle with which this folder is equipped project momentarily, and the condition of said measurement chip before and behind body fluid adhesion, and the measurement device which measures the specific component in body fluid from the detection result by this detection device and the display device which displays the measurement result by this measurement device.
[0016] The blood sugar measuring device which is one of the operation gestalten of this

invention equips the folder part of the body of equipment with the measurement chip which are disposable Lancet (reusable puncture needle) and a disposable cartridge for colorimetry, it carries out a puncture to the skin by making Lancet project according to the spring force, and it extracts the blood from the skin. The tip of the measurement chip built into the above-mentioned folder is equipped with tube-like blood aspiration opening, and attracts blood according to capillarity. About the quantum approach, it is applicable with not only this colorimetric method but an electrode method.

[0017] The above-mentioned folder is equipped with the device in which even a blood doner site carries out movable [of the measurement chip point], and further, extraction opening of the above-mentioned measurement chip is equipped with the device energized in the direction in which a reusable puncture needle projects with elastic bodies, such as a spring, so that it may not be concerned with condition or the description of blood at climax of a user's skin but the skin may always be contacted.

[0018] If body fluid contacts the point of the above-mentioned measurement chip, a part of the body fluid will be attracted according to capillarity. Therefore, the above-mentioned measurement chip is equipped with hand control or a justification means to adjust a location automatically so that the amount of point may come near the blood doner site part.

[0019] It is also possible to adjust a location with a small actuator so that sensing of the front face of the skin may be carried out by the photosensor and body fluid extraction opening may come near the blood doner site part on the front face of the skin as another example of a mode.

[0020] In addition, near said here is a distance to which the body fluid drop which grew up to be a certain magnitude by the puncture contacts body fluid suction opening immediately. a body fluid drop required for measurement -- for example, supposing it is hemispherical, the radius of a semi-sphere will be computed from the volume. The result of having calculated the relation between need total body water and a body fluid drop radius is shown in drawing 6 . For example, supposing body fluid required for measurement is 2microL, it is necessary to arrange body fluid suction opening in the location, if it is 1mm or more, the body fluid more than the amount of need assays is required, a patient's burden becomes large, and it carries out continuation suction of the amount of need assays and is not more desirable than drawing 6 , if the radius of a body fluid drop is less than 1mm conversely, since it is 1mm preferably. Furthermore, in consideration of climax of the large skin of individual difference, it is necessary to arrange the above-mentioned measurement chip. Then, the above-mentioned folder carried out movable [of the above-mentioned measurement chip] to the upper and lower sides and right and left, and is equipped with the device which keeps the optimal the distance of a bleeding part and body fluid suction opening so that climax of the large skin of individual difference can be taken into consideration.

[0021] The above-mentioned measurement chip built into the above-mentioned folder attracts [body fluid may enter the clearance made between the skin and the above-mentioned measurement chip, and] body fluid and is not desirable when whenever [to the skin / setting-angle] is small. Furthermore, the above-mentioned measurement chip takes [the rate which permeates a capillary tube falls and / body fluid suction] time amount and is not more desirable than the effect of a self-weight of body fluid, if whenever [to the skin / setting-angle] becomes large when the body fluid extraction directions are gravity and the reverse sense. Moreover, when the body fluid extraction directions are gravity and the same direction, the rate which permeates a capillary tube from the effect of a self-weight of body fluid hardly influences whenever [to the skin of the above-mentioned measurement chip / setting-angle].

[0022] 20 seconds of holding a quiescent state are a limitation for a patient with trouble in the fall of eyesight or a hand. For that, body fluid suction time amount has less than 20 desirable seconds. When it takes into consideration that the time amount which avoids that body fluid enters the clearance made between the skin and the above-mentioned measurement chip, and body fluid suction takes is less than 20 seconds, from drawing 5 whenever [setting-angle / of the above-mentioned measurement chip] When the body fluid extraction directions are gravity and the reverse sense (drawing 5 , continuous line), ten - 50 degrees are desirable, and when the body fluid extraction directions are gravity and the same direction (drawing 5 , broken line),

blood inhalation time amount does not approach an include angle, but is always less than 20 seconds, and is desirable as whenever [setting-angle]. [of ten - 90 degrees]
[0023] As shown in the mimetic diagram (a) of drawing 7 , whenever [setting-angle / of this body fluid extraction opening], and the relation of body fluid suction time amount are considered to be the axisymmetric flows in the capillary tube which stood blood extraction in the direction of facing up, and are analyzed based on the following equation of motion (dimension[non-]-izing) in consideration of being laminar-flow flow.
[0024]
[Equation 1]

$$\theta = -\frac{\xi}{\sin\beta} - \frac{1}{\sin^2\beta}\ln(1-\xi\sin\beta)$$

θ : 無次元時間　ξ : 無次元長さ

β : 取り付け角度

[0025] On the contrary, when gravity and the body fluid extraction direction are the same directions, as it was shown in drawing 7 (b), when it went caudad from the upper limit of a capillary tube and blood flowed, based on the following equation of motion, it analyzed similarly.
[0026]
[Equation 2]

$$\theta = \frac{\xi}{\sin\beta} - \frac{1}{\sin^2\beta}\ln(1+\xi\sin\beta)$$

θ : 無次元時間　ξ : 無次元長さ

β : 取り付け角度

[0027] The gestalt of desirable operation of the body fluid component measuring device of this invention is further explained using a drawing. Drawing 1 shows a general view of a blood sugar measuring device, equips the interior with the measurement chip 4 a disposable reusable puncture needle (not shown) and its drive, and for blood sugar colorimetric measurement, and is equipped with the display 1 which displays the optical system which measures the coloration of a chip, a calculation function, and its result. In the case of self-blood sugar determination etc., a patient equips with the measurement chip 4 and a reusable puncture needle 5 the folder 3 prepared in the skin puncture side of the body lower part. The sectional view of this folder 3 is shown in drawing 2 . In this equipment, a folder part can be removed, the body which shows the above-mentioned folder shown in drawing 2 equipped with the above-mentioned measurement chip 4 and a reusable puncture needle 5 to drawing 1 is equipped with it, and as shown in drawing 4 , it is pressed against the skin. Moreover, since it is possible to observe a puncture part and the condition of blood, this folder considers as the product made of transparence resin, and is further equipped with opening.
[0028] As shown in drawing 3 , a measurement chip is equipped with cylinder-like blood extraction opening, and consists of cartridges made of resin which built the test paper which causes color reaction in the rectangular parallelepiped part. The measurement chip wearing part of a folder is equipped with the range adjustment dial 7 which adjusts a horizontal location, and moves the location of the above-mentioned measurement chip 4 near the bleeding part in consideration of the climax condition of a user's skin etc. As shown in drawing 4 , specifically, the location of blood extraction opening of a measurement chip is adjusted to the radius of 1mm near a blood drop and from a puncture location in a location like front [the above-mentioned measurement chip migration] 11 (broken line) and the above-mentioned 12 after measurement chip migration (continuous line). With this equipment, the range adjustment dial 7 performs migration manually. A small actuator may be used for distance accommodation.
[0029] Moreover, even if it doubles the location of a longitudinal direction, the skin may rise and the blood extraction opening tip of a measurement chip may be plugged up depending on the direction. It consists of equipment of this invention so that a measurement chip may always be energized to a skin side with the elastic body 6 made from a spring. And by balance of the climax

condition of a user's skin, and an elastic body 6, as shown in drawing 4 , the above-mentioned measurement chip tip contacts a skin front face. The folder part of a measurement chip was constituted so that the include angle of the skin contact surface of blood extraction opening of a measurement chip and a body might turn into 30 degrees.
[0030] A puncture is performed in this condition and a body is held in the condition as it is. From the tip of the above-mentioned measurement chip arranged near the bleeding part, blood is attracted and the test paper discolors. The discoloration is measured optically, it is converted into the blood sugar level, and a result is displayed. With the alarm of measurement termination, it takes care that blood does not adhere to the above-mentioned folder, and a body is separated from the skin.

[Translation done.]

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CLAIMS

[Claim(s)]
[Claim 1] The body-fluid component measuring device characterized by to have a justification means to adjust the body fluid extraction location of this body fluid extraction means, in the body fluid component measuring instrument equipped with a body fluid extraction means to extract the body fluid leaked by carrying out the puncture of the skin with the reusable puncture needle and this reusable puncture needle which carry out the puncture of the skin, and a body fluid component measurement means to measure this amount of body fluid components.
[Claim 2] The body fluid component measuring device according to claim 1 characterized by for this body fluid extraction means being a means to extract body fluid from body fluid extraction opening according to capillarity, and this justification means being a means to which this body fluid extraction opening is moved near the blood collecting section of the skin.
[Claim 3] Claim 1, the body fluid component measuring device of two publications with which this body fluid extraction means is equipped with a tube-like body fluid doner site, the body fluid extraction directions are the gravity direction and hard flow, and this justification means is characterized by being a means by which this justification means adjusts the include angle of this body fluid doner site and the skin contact surface to ten - 50 degrees.
[Claim 4] Claim 1, the body fluid component measuring device of two publications with which this body fluid extraction means is equipped with a tube-like body fluid doner site, the body fluid extraction direction is the gravity direction, and this justification means is characterized by being a means by which this justification means adjusts the include angle of this body fluid doner site and the skin contact surface to ten - 90 degrees.
[Claim 5] The body fluid component measuring device according to claim 1 to 4 characterized by this justification means being a means to which the location of body fluid extraction opening of this body fluid extraction means is moved to the contact location at the time of total body water measurable [with this body fluid measurement means] leaking out from the skin.
[Claim 6] The body fluid component measuring device according to claim 1 to 5 characterized by this body fluid extraction means and this body fluid component measurement means being removable cartridges.
[Claim 7] The body fluid component measuring device according to claim 1 to 6 characterized by for the skin contact side of the case of this body fluid component measuring device consisting of resin of transparence, and equipping it with opening which can check a puncture location.

[Translation done.]

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DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]
[Drawing 1] The whole body fluid component measuring device external view of this invention.
[Drawing 2] Drawing of longitudinal section of the folder part of the body fluid component measuring device of this invention.
[Drawing 3] The perspective view of a measurement chip.
[Drawing 4] Drawing of longitudinal section showing the movable device of a measurement chip.
[Drawing 5] The related Fig. of whenever [setting-angle / of a measurement chip], and blood aspiration time amount.
[Drawing 6] The related Fig. of need total body water and a body fluid drop radius.
[Drawing 7] The mimetic diagram which analyzes the relation of whenever [body fluid extraction opening setting-angle / of body fluid suction time amount and a measurement chip].
[Description of Notations]
1 Display Device
2 Measurement Initiation Switch
3 Folder
4 Measurement Chip
5 Reusable Puncture Needle
6 Elastic Body
7 Range Adjustment Dial
8 Photo Detector
9 Light Emitting Device
10 Substrate
11 Moving Part (before Migration)
12 Moving Part (after Migration)

[Translation done.]

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審査請求　未請求　請求項の数７　ＯＬ　（全５頁）

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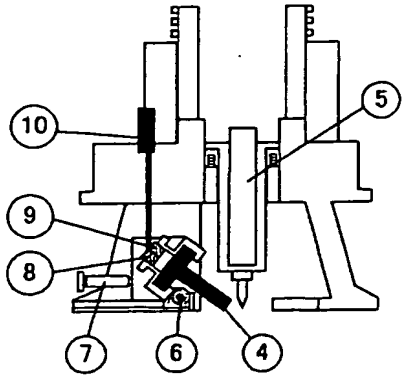
Ｆターム(参考)　4C038 KK10 KL01 KL07 KL09 KY04

(54)【発明の名称】　体液成分測定装置

(57)【要約】
【課題】　穿刺具および体液成分測定部を備え、穿刺・体液採取・測定・結果表示を連続的に行うことができ、出液された体液を短時間でかつ確実に採取することができる体液成分測定装置を提供する。
【解決手段】　皮膚を穿刺する穿刺針、該穿刺針により皮膚を穿刺することにより漏出した体液を採取する体液採取手段、及び該体液成分量を測定する体液成分測定手段を備えた体液成分測定器において、該体液採取手段の体液採取位置を調整する位置調整手段を備えることを特徴とする体液成分測定装置。



1

【特許請求の範囲】

【請求項１】　皮膚を穿刺する穿刺針、該穿刺針により皮膚を穿刺することにより漏出した体液を採取する体液採取手段、及び該体液成分量を測定する体液成分測定手段を備えた体液成分測定器において、該体液採取手段の体液採取位置を調整する位置調整手段を備えることを特徴とする体液成分測定装置。

【請求項２】　該体液採取手段が毛管現象により体液採取口から体液を採取する手段であり、該位置調整手段が該体液採取口を皮膚の採血部近傍に移動させる手段であることを特徴とする請求項１記載の体液成分測定装置。

【請求項３】　該位置調整手段が、該体液採取手段がチューブ状の体液採取部を備え、体液採取方向が重力方向と逆方向であり、該位置調整手段が、該体液採取部と皮膚接触面との角度を１０度～５０度に調整する手段であることを特徴とする請求項１、２記載の体液成分測定装置。

【請求項４】　該位置調整手段が、該体液採取手段がチューブ状の体液採取部を備え、体液採取方向が重力方向であり、該位置調整手段が、該体液採取部と皮膚接触面との角度を１０度～９０度に調整する手段であることを特徴とする請求項１、２記載の体液成分測定装置。

【請求項５】　該位置調整手段が、該体液採取手段の体液採取口の位置を該体液測定手段で計測可能な体液量が皮膚から漏出した時点における接触位置まで移動させる手段であることを特徴とする請求項１～４記載の体液成分測定装置。

【請求項６】　該体液採取手段及び該体液成分測定手段が着脱可能なカートリッジであることを特徴とする請求項１～５記載の体液成分測定装置。

【請求項７】　該体液成分測定装置の筐体の皮膚接触側が透明の樹脂で構成され、穿刺位置が確認可能な開口部を備えることを特徴とする請求項１～６記載の体液成分測定装置。

【発明の詳細な説明】

【０００１】

【発明の属する技術分野】本発明は、血糖値など、体液に含まれる特定成分を測定することができ、尚且つ穿刺・体液採取・測定・結果表示を一体の操作で行うことができるように構成された、体液成分測定器に関する。

【０００２】

【従来の技術】近年、生活環境の変化から糖尿病患者が急増している。糖尿病患者は、日常の血糖値の変動を正常な範囲に保つことが必要であり、患者自身が自己の血糖値をモニターする自己血糖値測定（SMBG）が推奨されている。

【０００３】血糖値の測定方法の一つに、血中グルコース量に応じて呈色する試験紙に血液を浸透させ、その呈色の度合いを光学的に測定して血糖値に換算する方法が広く使用されている。また別の方法として酵素電極を使

2

用し、試験片に血液を接触させることにより酵素反応を起こさせ、電気化学的反応を介して発生した陽極電流値を血糖値に換算する方法が使用されている。

【０００４】比色測定に際しては、患者はランセットなどの穿刺具で指先などの皮膚を穿刺した後、出てきた血液を試験紙に浸透させる。かかる試験紙を測定装置に装着して血糖値を求める。従来の自己血糖値測定器は穿刺具と血糖測定器が別々であるため、皮膚を穿刺する動作と試験紙に血液を浸透させる動作との二つの動作をする必要があり、不慣れな患者、あるいは視力の低下した患者にとってはきわめて困難である。そこで、上記のような不具合を解決しようとするものとして、特開平１３－３０９９０５号公報や特開２０００－１１６６２６号公報に記載のような、穿刺具と血糖測定器が一体となったものが開発されている。

【０００５】一方、測定に必要な血液を確保する為に採血は、一般的に毛細血管が集中した指先で行なわれるが、指先は神経が集中する部位でもあり、痛みを伴い採血時の患者の負担となり、患者が、測定回数を恣意的に減らすなど健康管理上も問題となる場合がある。その為、特開平９－３０４３２９号公報には、一回の採血量を数μｌといった少量で測定できる装置が開示され、また別の方法としてWO９７－４３９６２号公報には痛みの少ない腕などでも採決することが可能な採血器具も開示されている。

【０００６】

【発明が解決しようとする課題】血糖測定は、毎日数回測定することが多く、患者のコンプライアンスを上げる為には、痛みの軽減が至上命題であり、如何に少量の血液量で、如何に痛みの少ない部分から効率的に血液を採取するかは重要な問題である。

【０００７】例えば、特開2001－309905号公報記載の装置では、電動ポンプを用いて吸引する方法が開示されている。しかし吸引ポンプを装着する必要から装置が大型化し、重量も重くなり携帯性と言う面では好ましくない。さらに、電動ポンプの動力源に電池を用いるためコストの面からも好ましくない。

【０００８】更にこのような患者は、血液の性状やヒトの体型についても個人差が大きく、同じ装置でもうまく測定できる人もいれば、測定に失敗する人もあり、一回の測定に２回も穿刺する必要がある場合も生じ、コンプライアンス低下の要因となっている。

【０００９】本発明の目的は、穿刺具および体液成分測定部を備え、穿刺・体液採取・測定・結果表示を連続的に行うことができ、出液された体液を短時間でかつ確実に採取することによって測定の確実性を高め、携帯性、および、コスト面に優れた、体液成分測定器を提供することにある。

【００１０】

【課題を解決するための手段】かかる課題に対して本発

明者は鋭意検討した結果、以下の装置を見出した。すなわち本発明は、皮膚を穿刺する穿刺針、該穿刺針により皮膚を穿刺することにより漏出した体液を採取する体液採取手段、及び該体液成分量を測定する体液成分測定手段を備えた体液成分測定器において、該体液採取手段の体液採取位置を調整する位置調整手段を備えることを特徴とする体液成分測定装置を提供するものである。

【００１１】また本発明は、かかる体液採取手段が毛管現象により体液採取口から体液を採取する手段であり、該位置調整手段が該体液採取口を皮膚の採血部近傍に移動させる手段、態様例としては常に皮膚側に付勢する弾性手段を備えることを特徴とする体液成分測定装置を提供するものである。

【００１２】更に本発明は、該位置調整手段が、該体液採取手段がチューブ状の体液採取部を備え、体液採取方向が重力と逆向きの場合、該位置調整手段が、該体液採取部と皮膚接触面との角度を１０度～５０度に調整する手段であり、逆に体液採取方向が重力方向の場合、該位置調整手段が、該体液採取部と皮膚接触面との角度を１０度～９０度に調整する手段であることを特徴とする体液成分測定装置を提供するものである。

【００１３】また本発明は、かかる位置調整手段が、該体液採取手段の体液採取口の位置を該体液測定手段で計測可能な体液量が皮膚から漏出した時点における接触位置まで移動させる手段であることを特徴とする体液成分測定装置を提供するものである。

【００１４】

【発明の実施の形態】本発明の体液成分測定装置の好ましい実施形態を血糖測定装置を例に説明する。かかる装置は血糖測定に限らず各種体液成分測定装置に適用可能なものである

【００１５】本発明の体液成分測定器は、本体と着脱可能な穿刺針、および、着脱可能な測定チップをこの本体のフォルダ部分に装着して使用する様に構成され、皮膚を穿刺して体液を採取しこれに含まれる特定成分を測定するための測定器である。本体部分には、このフォルダが備える穿刺針を瞬間的に突出させるための穿刺機構、および、体液付着前後の前記測定チップの状態を検出するための検出機構と、この検出機構による検出結果より体液中の特定成分を測定する測定機構、及びこの測定機構による測定結果を表示する表示機構を有する。

【００１６】本発明の実施形態の一つである血糖測定装置は、使い捨てのランセット（穿刺針）および使い捨ての比色定量用カートリッジである測定チップを装置本体のフォルダ部分に装着し、バネ力によりランセットを突出させることで皮膚に穿刺し、皮膚からの血液を採取する。上記フォルダに組込まれた測定チップの先端は、チューブ状の血液吸引口を備え、血液を毛管現象により吸引する。定量方法については、かかる比色法に限らず電極法でも適用可能である。

【００１７】上記フォルダには測定チップ先端部を血液採取部位まで可動する機構を備えており、更に上記測定チップの採取口は、使用者の皮膚の盛り上がりに具合や血液の性状に関わらず常時皮膚に接触するように、バネなどの弾性体により穿刺針が突出する方向に付勢される機構を備えている。

【００１８】上記測定チップの先端部に体液が接触すると、その体液の一部が毛管現象により吸引される。従って上記測定チップは、先端部分が血液採取部分近傍に来るように手動、或いは自動で位置を調整する位置調整手段を備える。

【００１９】別の態様例としては、光センサーで皮膚の表面をセンシングし、体液採取口が皮膚表面の血液採取部分近傍に来るように小型アクチュエータで位置を調節することも可能である。

【００２０】尚、ここで言う近傍とは、穿刺によりある大きさに成長した体液滴が直ちに体液吸引口に接触する距離である。測定に必要な体液滴、例えば半球状であるとすると、その体積から、半球の半径が算出される。必要体液量と体液滴半径の関係を計算した結果を図６に示す。例えば、測定に必要な体液が２μLであるとすると、図６より、体液滴の半径は1mmであるから、その位置に体液吸引口を配置する必要があり、1mm以上だと必要検定量以上の体液が必要であり、患者の負担が大きくなり好ましくなく、逆に1mm以内だと必要検定量を連続吸引できない場合があり好ましくない。さらに、個人差の大きい皮膚の盛りあがりを考慮して、上記測定チップを配置する必要がある。そこで、上記フォルダは、個人差の大きい皮膚の盛りあがりを考慮できるよう、上記測定チップを上下、および左右に可動して、出液部位と体液吸引口の距離を最適に保つ機構を備えている。

【００２１】上記フォルダに組込まれた、上記測定チップは皮膚に対する取り付け角度が小さい場合、皮膚と上記測定チップの間にできる隙間に体液が入り込み体液を吸引できない場合があり好ましくない。さらに、上記測定チップは、体液採取方向が重力と逆向きの場合、皮膚に対する取り付け角度が大きくなると、体液の自重の影響より毛管を浸透する速度が低下し、体液吸引に時間を要し好ましくない。また、体液採取方向が重力と同じ向きの場合、体液の自重の影響より毛管を浸透する速度は、上記測定チップの皮膚に対する取り付け角度にほとんど影響しない。

【００２２】視力の低下、あるいは手の不自由な患者にとって、静止状態を保持するのは２０秒が限界である。このためには体液吸引時間は２０秒以内が好ましい。皮膚と上記測定チップの間にできる隙間に体液が入り込むのをさけ、体液吸引に要する時間が２０秒以内であることを考慮すると、図５より上記測定チップの取り付け角度は、体液採取方向が重力と逆向きの場合（図５、実

線）、１０度～５０度が好ましく、体液採取方向が重力と同じ向きの場合（図５、破線）、血液吸入時間は角度に寄らず常に２０秒以内であり、取り付け角度としては１０度～９０度が好ましい。

【００２３】かかる体液採取口の取り付け角度と体液吸引時間の関係は、図７の模式図（a）に示すように、血液採取を上向き方向に立てた毛細管内の軸対称流れと考え、層流流れであることを考慮して下記の運動方程式（無次元化）に基づいて解析する。

【００２４】

【数１】

$$\theta = -\frac{\xi}{\sin\beta} - \frac{1}{\sin^2\beta}\ln(1-\xi\sin\beta)$$

θ：無次元時間　ξ：無次元長さ

β：取り付け角度

【００２５】逆に、重力と体液採取方向が同じ向きの場合、図７(b)に示すように毛管の上端から下方に向かって血液が流れる場合も同様に下記運動方程式に基づいて解析した。

【００２６】

【数２】

$$\theta = \frac{\xi}{\sin\beta} - \frac{1}{\sin^2\beta}\ln(1+\xi\sin\beta)$$

θ：無次元時間　ξ：無次元長さ

β：取り付け角度

【００２７】本発明の体液成分測定装置の好ましい実施の形態について図面を用いて更に説明する。図１は血糖測定装置の概観を示したものであり、内部には使い捨ての穿刺針（図示せず）、及びその駆動機構、血糖比色測定用の測定チップ４を備え、チップの呈色を計測する光学系、演算機能及びその結果を表示する表示部1を備える。自己血糖測定などの場合、患者は測定チップ４及び穿刺針５は本体下部の皮膚穿刺側に設けられたフォルダ３に装着する。かかるフォルダ３の断面図を図２に示す。かかる装置においてフォルダ部分は取り外しが可能であり、上記測定チップ４、および穿刺針５を装着した図２に示す上記フォルダを図１に示す本体に装着し、図４に示すように皮膚に押し当てる。また穿刺箇所、血液の状態を観察することが可能とする為に、かかるフォルダは透明樹脂製とし、更に開口部を備える。

【００２８】測定チップは図３に示すように、円筒状の血液採取口を備え、呈色反応を起こす試験紙を直方体部分に内蔵した樹脂製カートリッジで構成される。フォルダの測定チップ装着部位は、水平方向の位置を調整する距離調整ダイヤル７を備え、使用者の皮膚の盛りあがり具合等を考慮して、上記測定チップ４の位置を出血部位近傍に移動させる。具体的には、図４に示すように、上記測定チップ移動前１１（破線）および上記測定チップ移動後１２（実線）のように測定チップの血液採取口の位置を血液滴付近、穿刺位置から半径１ｍｍに位置に調整する。かかる装置では移動は距離調整ダイヤル７により手動で行う。距離調節に小型のアクチュエータを使ってもかまわない。

【００２９】また、左右方向の位置を合わせても、皮膚の盛り上がり方によっては測定チップの血液採取口先端を塞いでしまう場合がある。本発明の装置では、測定チップをバネ製の弾性体６により常に皮膚側に付勢するように構成される。そして使用者の皮膚の盛りあがり具合と弾性体６とのバランスにより、図４に示すように上記測定チップ先端は皮膚表面に接触する。測定チップの血液採取口と本体の皮膚接触面の角度が３０度となるように測定チップのフォルダ部分を構成した。

【００３０】この状態で穿刺を行い、そのままの状態で本体を保持する。出血部位近傍に配置された上記測定チップの先端より血液を吸引し、試験紙が変色する。その変色を光学的に測定し、血糖値に換算され結果が表示される。測定終了のアラームとともに上記フォルダに血液が付着しないよう注意して本体を皮膚から離す。

【図面の簡単な説明】

【図１】本発明の体液成分測定装置の全体外観図。

【図２】本発明の体液成分測定装置のフォルダ部分の縦断面図。

【図３】測定チップの斜視図。

【図４】測定チップの可動機構を示す縦断面図。

【図５】測定チップの取り付け角度と血液吸引時間の関係図。

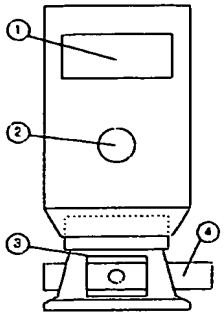
【図６】必要体液量と体液滴半径の関係図。

【図７】体液吸引時間と測定チップの体液採取口取り付け角度の関係を解析する模式図。

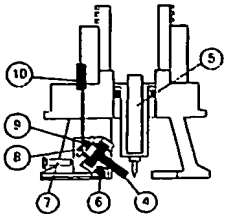
【符号の説明】

１　表示機構
２　測定開始スイッチ
３　フォルダ
４　測定チップ
５　穿刺針
６　弾性体
７　距離調整ダイヤル
８　受光素子
９　発光素子
１０　基板
１１　可動部（移動前）
１２　可動部（移動後）

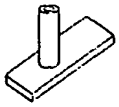
【図１】



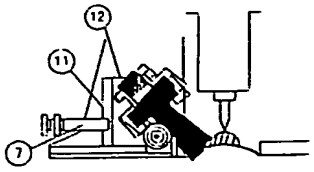
【図２】



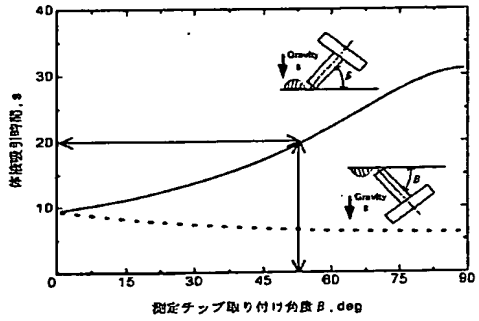
【図３】



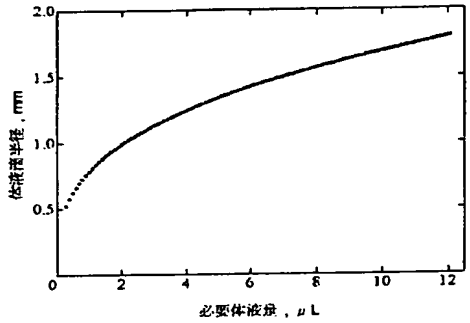
【図４】



【図５】



【図６】



【図７】